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FOLEY AND LARDNER LLP			FETTEROLF, BRANDON J	
SUITE 500			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,644	BUA, JAY	
Examiner	Art Unit		
Brandon J. Fetterolf, PhD	1642		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 July 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3,5-13,15-21 and 23-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3, 5-13, 15-21 and 23-28 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ .
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date . 5) Notice of Informal Patent Application
6) Other: ____ .

DETAILED ACTION

Response to the Amendment

The Amendment filed on 7/10/2007 in response to the previous Non-Final Office Action (4/10/2007) is acknowledged and has been entered.

Claims 1-3, 5-13, 15-21 and 23-28 are currently pending.

The Declaration under 37 CFR 1.132 filed on 7/10/2007 by Jean L. Fourcroy, M.D. is insufficient to overcome the rejection of claims 1-3, 5-13, 15-21 and 23-28 based upon Atkinson et al. (Cancer Epidemiology, Biomarkers & Prevention 1999; 8: 863-866, IDS) as evidenced by Boyd et al. (J. Nat. Cancer Inst. 1995; 87: 670-675, *of record*) and Kolb et al. (Radiology 2002; 225: 165-175, *of record*) in view of Mauvais-Jarvis (US 4,919,937, 1990, IDS) as evidenced by Mauvais-Jarvis (Cancer Research 1986; 46: 1521-1525, *of record*) and in further view of Yamaguchi et al. (US 5,820,877, 1998) as set forth in the last Office action because: Jean. L. Fourcroy's argument (last sentence, item 7) appears to be directed to it being impossible to exchange tamoxifen with its metabolite (4-hydroxy tamoxifen) to treat breast density in view of the combined teachings of the prior art references. For example, Jean L. Fourcroy argues that tamoxifen and 4-hydroxy-tamoxifen are distinct chemicals; and, that tamoxifen is metabolized in the liver by P450 enzymes. However, these arguments do not appear to address how this is a specific teaching away from the combination to arrive at the claimed invention. As set forth in the previous office action, as well as stated in the declaration (second sentence, item 11), one of ordinary skill in the art would recognize that 4-hydroxy tamoxifen overcomes the harmful side effects associated with oral administration of 10 to 30 mg/day of tamoxifen such as paradoxical stimulation of the ovaries by passing through the cutaneous barrier and being taken up directly by the estrogen receptors. Thus, the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or *expected beneficial result* would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983) Moreover, while the declaration (Item 9) sets forth that tamoxifen and 4-hydroxy tamoxifen elicit different responses in mammary cells, e.g. tamoxifen initiates apoptosis in p53- normal human mammary cells vs. estrogen sulphatase activity inhibition in mammary cancer cells by 4-hydrox tamoxifen, this does not appear to be a true comparison between

their respective activity because different cells were used (cancerous versus normal mammary cells) and different activities were measured. Moreover, as stated in the Declaration (3rd sentence, Item 8), tamoxifen is dependent on cytochrome p450 enzyme for metabolism to a more active metabolite, such as 4 hydroxy tamoxifen. As such, these examples do not appear to be a true comparison between their respective activity because tamoxifen relies on enzymes for its metabolism to its more active metabolite, 4-hydroxy tamoxifen. Thus, it is not clear how the declaration provides a clear teaching away from the combination of the two main references.

Rejection Withdrawn:

The rejection of claims 13, 15-21, 23 and 25-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, e.g., a NEW MATTER REJECTION, is withdrawn in view of Applicants amendments

The rejection of claims 1-3, 5-10, 12-13, 15-20, 15-21, 24-25 and 27-28 under 35 U.S.C. 103(a) as being unpatentable over Atkinson et al. (Cancer Epidemiology, Biomarkers & Prevention 1999; 8: 863-866, IDS) as evidenced by Boyd et al. (J. Nat. Cancer Inst. 1995; 87: 670-675, *of record*) and Kolb et al. (Radiology 2002; 225: 165-175, *of record*) in view of Mauvais-Jarvis (US 4,919,937, 1990, IDS) as evidenced by Mauvais-Jarvis (Cancer Research 1986; 46: 1521-1525, *of record*) and in further view of Yamaguchi et al. (US 5,820,877, 1998) is withdrawn in view of Applicants arguments. In particular, the rejection has been withdrawn because Yamaguchi does not explicitly teach isopropyl myristate.

New Rejections upon Reconsideration:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-13, 15-20, 15-21, 24-25 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson et al. (Cancer Epidemiology, Biomarkers & Prevention 1999; 8: 863-866, IDS) as evidenced by Boyd et al. (J. Nat. Cancer Inst. 1995; 87: 670-675, *of record*) and Kolb et al. (Radiology 2002; 225: 165-175, *of record*) in view of Mauvais-Jarvis (US 4,919,937, 1990, IDS) as evidenced by Mauvais-Jarvis (Cancer Research 1986; 46: 1521-1525, *of record*) and in further view of Ueda et al. (US 5,045,553).

Atkinson et al teach the effects of tamoxifen on mammographic density, wherein mammograms from 94 women who had received tamoxifen for breast cancer and 188 women (without breast cancer) who had not received tamoxifen were visually classified according to the Wolfe pattern (abstract). Specifically, the reference teaches (page 865, Table 2 and page 864, 1st column, *Data Analysis*) administration of tamoxifen to patients having N1, P1, P2 or DY breast density Wolfe patterns, wherein N1 represents the most lucent pattern and DY represents the most dense pattern. The reference further teaches (page 865, Table 2 and 2nd column, last paragraph) that tamoxifen treatment resulted in a reduction in mammographic breast density. As such, Atkinson et al. conclude (page 866, 1st column, last paragraph) that an additional benefit of reducing breast density by tamoxifen treatment may relate to the effectiveness of mammographic breast screening, wherein the reduction in breast density may provide benefits in terms of diagnosis at an earlier physiological stage and, thus, improved survival rates from breast cancer. Thus, while Atkinson et al. does not explicitly teach that the breast tissues are class III and/or class IV dense breast tissue, a patient having a the most dense DY breast pattern and/ or a P2 pattern on the Wolfe scale would meet the limitation of a Class III or Class IV dense breast composition because as evidenced by Kolb et al., the American College of Radiology has developed a classification system for breast composition, wherein class 3 is breast tissue heterogeneously dense and class 4 is highly dense (page 166, 3rd column, 1st paragraph). Hence, it does not appear that the claimed limitation and/or category result in a manipulative difference between the prior arts disclosure. Moreover, although Atkinson et al. does not explicitly teach that the breast tissues having a DY pattern includes dense tissue that is diffuse or nodular, the claimed limitation would be an inherent property of breast tissue

characterized as DY because as evidenced by Boyd et al., DY describes a breast in which the parenchyma is occupied by both diffuse or nodular densities (page 670, 2nd column, 2nd paragraph). Thus, it does not appear that the claimed limitation results in a manipulative difference in the products used when compared to the prior arts disclosure. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int.

Atkinson et al. do not explicitly teach percutaneous administration of 4-hydroxy tamoxifen to a patient having class III or class IV dense breast composition.

Mauvaris-Jarvis et al. teach (column 4, lines 46-53) a method of treating conditions of the breast comprising administering percutaneously an aqueous alcoholic gel comprising trans-4-hydroxy tamoxifen, wherein the aqueous alcoholic gel enables percutaneous penetration to take place and comprises Carbopol ®, ethyl alcohol/water and 0.15g of 4-hydroxy tamoxifen (column 3, lines 29-39). With regards to the conditions of the breast, the patent teaches (column 4, lines 37-39) that the breast conditions include, but are not limited to, benign and cancerous conditions of the breast. Moreover, Mauvaris-Jarvis et al. teach that percutaneous administration of 4-hydroxytamoxifen overcomes the harmful side effects associated with oral administration of 10 to 30 mg/day of tamoxifen such as paradoxical stimulation of the ovaries by passing through the cutaneous barrier and being taken up directly by the receptors molecules in the tumors. In addition, Mauvaris-Jarvis et al. teach that 4-hydroxy tamoxifen is the active form of tamoxifen at the molecular level and has been shown to be twenty to one hundred times more active than tamoxifen as an anti-estrogen at the level of estrogen receptors (column 1, lines 24-32). Thus, while Mauvaris-Jarvis et al. do not specifically teach that the 4-hydroxy tamoxifen is administered as a racemic mixture of both trans and cis isomer, the claimed limitation would be an inherent property of the percutaneous administration of trans-4-hydroxy tamoxifen because as evidenced by Mauvais-Jarvis (Cancer Research 1986; 46: 1521-1525, IDS), percutaneous administration of the trans-4-OHTAM resulted in an equal yield of the cis and trans isomers of 4-OHTAM from breast tissue (page 1522,

2nd column, 6th paragraph). Thus, it does not appear that the claimed limitation results in a manipulative difference in the products used when compared to the prior arts disclosure. Lastly, although Mauvaris-Jarvis et al. teach that the 0.15g of 4-hydroxy is in The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int.

Mauvaris-Jarvis et al. do not explicitly teach that the alcoholic gel comprises 4-hydroxy tamoxifen, ethyl alcohol, isopropyl myristate and hydroxypropylcellulose.

Ueda et al. teach a pharmaceutical composition for percutaneous drug absorption comprising a percutaneous absorption promoter such as ethanol and/or isopropyl myristate, as well as a base for preparing said pharmaceutical composition, wherein the base includes, but is not limited to, hydroxypropyl cellulose (abstract, column 2, lines 52-58 and column 3, lines 4-12). Moreover, the patent teaches that the pharmaceutical composition is made up into an ointment using Carbopol gel ointment (column 3, lines 64-68).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to substitute oral tamoxifen administration to a patient suffering from class III as taught Atkinson et al. for percutaneous administration of 4-hydroxy tamoxifen administration in view of the teachings of Mauvaris-Jarvis. One would have been motivated to do so because as taught by Mauvaris-Jarvis, 4-hydroxy tamoxifen is well known in the art to be the active form of tamoxifen at the molecular level, and further, overcomes the harmful side effects associated with oral administration of 10 to 30 mg/day of tamoxifen such as paradoxical stimulation of the ovaries by passing through the cutaneous barrier and being taken up directly by the estrogen receptors. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by substituting oral tamoxifen administration to a patient suffering from class III as taught Atkinson et al. for percutaneous administration of 4-hydroxy tamoxifen administration in view of the teachings of Mauvaris-Jarvis, one would achieve a safe alternative to oral tamoxifen.

Moreover, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the alcoholic gel as taught by Maurvaris-Jarvis to include 4-hydroxy tamoxifen, ethyl alcohol, isopropyl myristate, and hydroxypropylcellulose in view of the teachings of Ueda.. One would have been motivated to do so because each has been taught in the prior art as being equivalents suitable for the same purpose. As such, one of ordinary skill in the art would have a reasonable expectation of success that by modifying the alcoholic gel as taught by Maurvaris-Jarvis to include 4-hydroxy tamoxifen, ethyl alcohol, isopropyl myristate, hydroxymethylcellulose and a phosphate buffer in view of the teachings of Ueda, one would achieve an effective formulation for percutaneous administration.

Lastly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the amount of 4-hydroxy tamoxifen per amount of gel as taught by Maurvaris-Jarvis. One would have been motivated to do so because the courts have found that differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Note: In order to expedite prosecution, the Examiner would like to respond to Applicants arguments for the previous rejections as they relate to the instant rejections. In particular, Applicants arguments pertaining to the combination of Atkinson and Mauvais-Jarvis. In response to these two cited references, Applicants assert that the obvious rejection is based in large part on the assumption that it would have been obvious to replace the tamoxifen used by Atkinson with the 4-hydroxy tamoxifen taught in the Mauvais-Jarvis patent because 4-hydroxy tamoxifen is known to be an active metabolite of tamoxifen, and because 4-hydroxy tamoxifen avoids some side effects associated with tamoxifen. However, Applicants assert that this is an inaccurate reflection of the state of the art. For example, Applicants assert that prior to the present invention there was no knowledge in the art that 4-hydroxy tamoxifen would be useful in a method to reduce breast density. Moreover, Applicants assert that the reported usefulness of tamoxifen did not provide a reasonable expectation that 4-hydroxy tamoxifen would be useful for reducing breast density. As further evidence on point, Applicants submit Dr. Fourcroy’s testimony in the form of a 1.132 Declaration

which provides evidence that it is not possible to extrapolate from Atkinson's use of tamoxifen described in the application. For example, Applicants assert that as explained by Dr. Fourcroy, it is important to understand that tamoxifen and 4-hydroxy tamoxifen are distinct agents, each with unique safety and efficacy profiles. Moreover, Applicants assert that as explained by Dr. Fourcroy, the final response element at the cellular level is dependent on the unique conformation of the estrogen receptor in the individual cell type. In addition, Applicants assert that Dr. Fourcroy testifies that the state of the art, as illustrated by the publications cited above, is such that tamoxifen and 4-hydroxy tamoxifen are known to have different modes of action. Thus, Applicants assert that according to Dr. Fourcroy, persons versed in this field understand that knowing that tamoxifen is useful in a given therapeutic regimen does not provide a reasonable basis for expecting that 4-hydroxy tamoxifen would be useful for the same purpose. Lastly, Applicants assert that Dr. Fourcroy testifies that the present invention provides significant advantages over the state of the art, particularly over the use of tamoxifen to reduce breast density because percutaneous 4-hydroxy tamoxifen offer important safety improvements. Therefore, Applicants assert that the foregoing demonstrates that it was known in the art that tamoxifen and 4-hydroxy tamoxifen are not biologically equivalent; and therefore, are not necessarily interchangeable for therapeutic purposes.

These arguments have been carefully considered, but are not found persuasive.

First, the Examiner acknowledges Applicants assertions that the basis for the obvious rejection is an inaccurate reflection of the state of the art. However, the Examiner recognizes that Applicants have not provided any arguments pertaining to this conclusion. In the instant case, as taught by Mauvais-Jarvis, 4-hydroxy tamoxifen is well known in the art to be the active form of tamoxifen at the molecular level, and further, overcomes the harmful side effects associated with oral administration of 10 to 30 mg/day of tamoxifen such as paradoxical stimulation of the ovaries by passing through the cutaneous barrier and being taken up directly by the estrogen receptors. Secondly, with regards to the Applicants arguments pertaining to the references individually, it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); *In re*

Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Maurvaris-Jarvis provides the motivation to substitute 4-hydroxy tamoxifen for tamoxifen in the method taught by Atkinson et al. because Maurvaris-Jarvis teaches that 4-hydroxy tamoxifen is well known in the art to be the active form of tamoxifen at the molecular level, and further, overcomes the harmful side effects associated with oral administration of 10 to 30 mg/day of tamoxifen such as paradoxical stimulation of the ovaries by passing through the cutaneous barrier and being taken up directly by the estrogen receptors. Lastly, with regards to Applicants arguments relating the Declaration, the Examiner acknowledges the declaration. However, it is not clear how the declaration provides a clear teaching away from the combination of the two main references for the reasons set forth above.

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson et al. (Cancer Epidemiology, Biomarkers & Prevention 1999; 8: 863-866, IDS) as evidenced by Boyd et al. (J. Nat. Cancer Inst. 1995; 87: 670-675, *of record*) and Kolb et al. (Radiology 2002; 225: 165-175, *of record*) in view of Ueda et al. (US 5,045,553) and Mauvais-Jarvis (US 4,919,937, 1990, IDS) as evidenced by Mauvais-Jarvis (Cancer Research 1986; 46: 1521-1525, *of record*) and in further view of Yamaguchi et al. (US 5,820,877, 1998, *of record*).

Atkinson et al in view of Ueda et al. and Mauvais-Jarvis, as applied to claims 1-3, 5-13, 15-21, 24-25 and 27-28, teach a method of reducing breast density in patient having class III or class IV dense breast, comprising percutaneously administering a pharmaceutical composition comprising 4-hydroxy tamoxifen, ethyl alcohol, isopropyl myristate and hydroxypropylcellulose.

Atkinson et al in view of Ueda et al. and Mauvais-Jarvis do not explicitly teach percutaneous administration of said pharmaceutical composition further comprising a phosphate buffer.

Yamaguchi et al. teach an alcoholic gel formulation suitable for percutaneous administration comprising a phosphate buffer, ethyl alcohol, isopropyl myristate and hydroxypropylcellulose or hydroxypropylmethylcellulose (Column 4, lines 38-42 and Column 11, lines 21-26).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the alcoholic gel as taught by Atkinson et al in view of Ueda et al. and Mauvais-Jarvis to include a phosphate buffer in view of the teachings of Yamaguchi et al.. One would have been motivated to do so because each has been taught in the prior art as being equivalents suitable for the same purpose. As such, one of ordinary skill in the art would have a reasonable expectation of success that by modifying the alcoholic gel as taught by Atkinson et al in view of Ueda et al. and Mauvais-Jarvis to include a phosphate buffer in view of the teachings of Yamaguchi et al., one would achieve an effective formulation for percutaneous administration.

Therefore, NO claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
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